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EXAMINER

KOSSON, ROSANNE

ART UNIT

PAPER NUMBER

1653

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Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION***Election/Restrictions***

Applicants' election without traverse of the species of one natural material, the material protein, two or more synthetic materials, and a therapeutic substance in claim 1 in the reply filed on June 21, 2006 is acknowledged. The elections of the species of a wound care product in claim 6, an extracellular matrix protein in claim 27 and a molecule in claims 30 in this same reply are also acknowledged. Applicants' election in claim 24 was not clear, as two species were elected. But, in a telephone conversation on June 27, 2006, Applicants, via their representative, Mr. John McDonald, elected the species of the two polymers polyvinyl alcohol (PVA) and polylactides (PLA) in claim 24. Since the last Office action on the merits of July 26, 2005, claims 1 and 6 have been amended. Claims 2-4, 7-8 and 10-23 have been canceled, claims 24-35 have been added, and claim 5 was withdrawn previously as being drawn to a non-elected invention. The limitations of claim 5, however, have been incorporated into claim 1. New claims 33-35 are withdrawn from prosecution as being drawn to a non-elected invention, as they recite a composition comprising different types of collagen (multiple proteins) and one polymer, which may be natural or synthetic. Accordingly, claims 1, 6, 9 and 24-32 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1653

Claim Rejections - 35 USC § 112, first and second paragraphs

In view of Applicants' amendments to the claims and the cancellation of claim 8, these rejections are withdrawn.

Claim Rejections - 35 USC § 102

Claims 1 and 6 are again rejected, and claims 24-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffee (WO 98/03267, see also equivalent US 6,252,129). This rejection was discussed in the previous Office action. Although Coffee does not explicitly disclose a composition of electroprocessed materials comprising one specified natural material and two specified synthetic materials, Applicants claims still recite a non-elected species in the claimed invention (one electroprocessed natural or synthetic polymer). These claims are rejected in accordance with MPEP §803.02, which states that "If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined."

As previously discussed, Coffee discloses compositions of electroprocessed fiber materials that incorporate an immiscible substance such as a biologically active ingredient (which is a therapeutic substance or a molecule) for applying to skin, a wound, a burn or a body cavity (see p. 2, 1st full paragraph; p. 3, last paragraph; and paragraph bridging pp. 5 and 6). These compositions are mats or webs (see p. 3, 1st full paragraph). The fiber mats may be

Art Unit: 1653

prepared from naturally occurring polymers such as fibrin or collagen (see p. 6, 1st full paragraph) or from synthetic biodegradable polymers such as polylactic acid, polyglycolic acid, polyvinyl alcohol or polyhydroxybutyric acid (see p. 4, 3^d paragraph). More than one type of electroprocessed fiber may be used to form a mat or web composition (see p. 18, 2^d full paragraph; paragraph bridging pp. 19 and 20; p. 23, 1st full paragraph; paragraph bridging pp. 32 and 33). Therefore, the rejection of record is maintained.

Claims 1, 6 and 9 are again rejected, and claims 24-26 and 30-32 are rejected, under 35 U.S.C. 102(b) as being anticipated by Martin et al. (US 4,043,331). This rejection was discussed in the previous Office action. As discussed above, although Martin et al. do not explicitly disclose a composition of electroprocessed materials comprising one specified natural material and two specified synthetic materials, Applicants claims still recite a non-elected species in the claimed invention (one or more electroprocessed synthetic polymers). These claims are rejected in accordance with MPEP §803.02, which states that if the elected species is not found, a second species will be searched, and the claims will be rejected if that species is found.

Martin et al. disclose electroprocessed fiber mats (abstract) for use in particular as bandages. Various polymers may be used to form the fibers, such as thermoplastic polymers, or those that may be spun from dispersions or solutions (column 4, lines 26-44; column 5, lines 21-29). Various immiscible substances such as biological components (therapeutic substances or molecules) can be incorporated within the mat (column 2, lines 35-46). When water-soluble polymers are electrospun, the polymers are first cross-linked with a suitable reagent to make them at least partially insoluble in aqueous media (see col. 4, lines 38-44). Martin et al. also disclose that fibers may be electrospun from multiple types of dissolved polymers. Each type of

Art Unit: 1653

polymer has its own favorable properties, and combining polymers allows fibers with desired characteristics to be produced in a controlled manner (see col. 1, lines 38-56). Therefore, the rejection of record is maintained.

Claims 1 and 6 are again rejected, and claims 24-32 are rejected, under 35 U.S.C. 102(b) as being anticipated by Doshi et al. ("Electrospinning process and applications of electrospun fibers," J Electrostatics 35:151-160, 1995). This rejection was discussed in the previous Office action. As discussed above, although Doshi et al. do not explicitly disclose a composition of electroprocessed materials comprising one specified natural material and two specified synthetic materials, Applicants claims still recite a non-elected species in the claimed invention (one electroprocessed natural or synthetic polymer). These claims are rejected in accordance with MPEP §803.02, which states that if the elected species is not found, a second species will be searched, and the claims will be rejected if that species is found.

Doshi et al. disclose three-dimensional compositions of electrospun fibers from solutions of water-soluble polymers, biopolymers, and liquid crystalline polymers. The fibrous compositions can be used for applying insecticide to plants, as non-woven fabric, as a wound dressing material or as an artificial blood vessel (see p. 152, 2^d full paragraph, and p. 159). Thus, an immiscible substance such as an insecticide, a wound-treating composition or blood is incorporated into the composition (a therapeutic substance or a molecule, although these substances are not exemplified by name). Composite materials may also be produced by changing the composition of the spinning solutions successively so that layers of different polymers are deposited on top of each other. Accordingly, the rejection of record is maintained.

Art Unit: 1653

Claims 1 and 6 are again rejected, and claims 24-32 are rejected, under 35 U.S.C. 102(e) as anticipated by Murphy et al. (US 2002/0172705), as evidenced by Koseki et al. (US 5,922,356). This rejection was discussed in the previous Office action. As discussed above, although Doshi et al. do not explicitly disclose a composition of electroprocessed materials comprising one specified natural material and two specified synthetic materials, Applicants claims still recite a non-elected species in the claimed invention (one electroprocessed natural and one electroprocessed synthetic polymer). These claims are rejected in accordance with MPEP §803.02, which states that if the elected species is not found, a second species will be searched, and the claims will be rejected if that species is found.

Murphy et al. disclose a composition comprising electroprocessed fibers, collagen (a natural material), and electroprocessed synthetic polymers (e.g., polycarbonate, polystyrene, polyvinylchloride, etc.) that is produced by culturing fibroblasts in a cell or tissue culture vessel that is electrostatically charged. The fibroblasts produce collagen as an extracellular matrix (see paragraphs 33 and 34). Cells located within the composition produce therapeutic substances (which are molecules) in the spaces between the fibers that are immiscible with the fibers (see paragraph 32).

In reply to Applicants' remarks, electroprocessing solutions to produce electroprocessed materials is not a claim limitation, nor is the exclusion of electrostatic charging as a technique. The portion of the specification cited by Applicants provides examples of electroprocessing techniques, not a limiting definition. In fact, the specification states on p. 3, lines 11-12, that any electroprocessing technique may be used, including, but not limited to, those named. Therefore, these features do not distinguish the claimed invention over the cited art. It is clear in the previous Office action that Koseki et al. were cited for their disclosure of collagen fiber

Art Unit: 1653

diameters, not for a disclosure of electroprocessing. Also, the use of glycosaminoglycan in sustained-release formulations, as noted by Applicants, is not relevant to the instant claims.

Therefore, the rejection of record is maintained.

Claim Rejections - 35 USC § 103

Claims 1, 6 and 9 are again rejected, and claims 24-32 are rejected, under 35 U.S.C. 103(a) as being unpatentable over Coffee (WO 98/03267), Martin et al. (US 4,043,331), Doshi et al. ("Electrospinning process and applications of electrospun fibers," J Electrostatics 35:151-160, 1995) and Murphy et al. (US 2002/0172705) in view of Mechanic (US 5,332,475). This rejection was discussed in the previous Office action.

Applicants assert that the amendments to the claims overcome the rejection and that the cited references do not teach or suggest an electroprocessed composition comprising one or more natural materials and one or more polymers. Applicants also assert that Examiner made this statement as well. In reply, Examiner did not make this statement. It is clear in the previous Office action that Examiner's position is that the cited references do not explicitly disclose a composition comprising three specified electroprocessed polymers, one of which is natural and two of which are synthetic. But it is also clear in the previous Office action that the cited references, in particular, Coffee and Doshi et al., teach the equivalence of electrospun fibers made of different biocompatible polymers as structural materials for making wound dressings and implants. More than one type of electroprocessed fiber, either natural or synthetic, may be used to form a mat or web composition (see Coffee, p. 18, 2^d full paragraph; p. 23, 1st full paragraph; paragraph bridging pp. 30 and 31) or a layered three-dimensional composition (see Doshi et al., p. 152, 2^d full paragraph, and p. 159). Although the cited references do not teach the claimed combination in one reference, it would have been prima

Art Unit: 1653

facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references to produce an electroprocessed material comprising one natural material and two synthetic materials. Each of these electroprocessed materials has been individually taught in the prior art to be successful when made into materials that are used for the same purpose as Applicants' material, i.e., a wound dressing (wound care product). The instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980), wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose, as the idea of combining them flows logically from their having been individually taught in the prior art. See also MPEP 21440.06. Applying the same logic to the instant claims, one of ordinary skill in the art would have reasonably expected to obtain an electroprocessed material used in the same ways as the claimed material with any one or with all three of the prior art polymers, i.e., a protein (collagen) and two synthetic polymers (polyvinyl alcohol and polylactide), because all of these polymers have been demonstrated in the prior art to be effective materials for wound dressings or implants, in particular wound dressings that promote cell growth and tissue repair.

Additionally, the strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). Martin et al. and Murphy et al. teach that each material in the composition is selected because of its desired biological, physical and/or chemical properties and that a selected combination of materials yields a composition that has the properties desired, e.g., permeability, thickness, biocompatibility and biodegradability. One of skill in the art would

Art Unit: 1653

recognize the benefits of a composition of electroprocessed materials comprising a natural material such as collagen for its biocompatibility, biodegradability and promotion of cell growth (as taught by Murphy et al., see paragraphs 1, 2, 22, 33 and 34) and a synthetic material such as polyurethane, which is a wettable polymer commonly used in wound dressings.

Polyurethane inhibits bleeding by promoting clotting, is porous and has a high surface area, which allows therapeutic substances to penetrate and blood from the wound to drain (see Martin et al., col. 2, lines 9-34). The synthetic polymers polyvinyl alcohol and polylactide have been used for a long time because they are biodegradable, inert, safe and water-soluble for simplified manufacturing (see Coffee, p. 19, last paragraph and p. 22, last paragraph). Organic solvents are more expensive than water and present waste disposal problems. Thus, one of ordinary skill in the art at the time that the invention was made would have been motivated to use a natural electroprocessed polymer and two or more synthetic electroprocessed polymers in order to produce a fibrous material that has multiple desirable properties, e.g., tissue compatibility and promotion of cell growth (from collagen), biodegradability, biocompatibility and easy manufacturing (from polyvinyl alcohol and/or polylactide), and inhibition of bleeding and improved delivery of therapeutic substances (from polyurethane).

Regarding claim 9, which recites that the electroprocessed material is cross-linked, Applicants assert that this claim is not obvious because claim 1 is not obvious in view of Mechanic, alone or in combination with the other cited references. One would not be motivated to combine these teachings because Mechanic discloses cross-linking collagen in the presence of a photo-oxidative catalyst only, and Mechanic does not disclose a therapeutic or cosmetic substance. In reply, as previously discussed, Mechanic discloses that proteins may be cross-linked by treating them with agents such as formaldehyde, glutaraldehyde, phthaloyl dichloride or adipoyl dichloride, or by introducing a mercaptan, for oxidation to a disulfide bond (see col. 1,

Art Unit: 1653

lines 23-42). Proteins may also be cross-linked by treating them with a photocatalyst, such as methylene blue, methylene green, riboflavin or fluorescein, and oxygen and subjecting them to photooxidation (see Mechanic, col. 2, line 64, to col. 3, line 2, and col. 5, line 59, to col. 6, line 11). Thus, a photo-oxidative catalyst is an alternative cross-linking agent, but it is not necessary. Moreover, exclusion of a photo-oxidative catalyst in the cross-linking step is not a claim limitation. Thus, a composition made by a method that does not use such an agent is not distinguished over the prior art. Also, it is clear that Mechanic was cited for his disclosure of cross-linking agents, not for his disclosure of a therapeutic substance.

Regarding claim 27, which recites that the protein is an extracellular matrix protein, collagen is an extracellular matrix protein.

In view of the foregoing, the rejection of record is maintained.

Double Patenting- Obviousness Type

Claims 1, 6 and 9 are again provisionally rejected, and claims 24-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 18-42 of copending Application No. 10/447,670. This rejection was discussed in the previous Office action. Claims 1-17 of copending Application No. 10/447,670 were amended to claims 1-3 and 18-42 since the last Office action on the merits in the instant case. As previously discussed, the copending claims are drawn to electrospun collagen fibers. The amended claims have the added limitation that the fibers have a banding pattern at a spacing of about 65-67 nm. It is not clear if the spacing of 65-67 nm refers to the width of the bands, the distance between two bands, or a feature of native mammalian collagen. In any case, this feature is either imparted by the apparatus that produces the material made of the spun collagen fibers, or it is naturally present, but this feature does not materially alter the

Art Unit: 1653

collagen fibers. The composition in the copending claims is drawn to one species recited in the instant claims, although some of the instant claims are broader in that they do not recite a particular fiber diameter or pore size in a material made of electroprocessed collagen (which includes electrospun collagen).

In their Response, Applicants note that they do not wish to file a terminal disclaimer, because the amendments to the claims overcome the rejections, their independent claims are patentably distinct, and the pending independent claims are not limited by fiber diameter or the inclusion of engineered tissue. In reply, as discussed above, the amendments do not overcome the outstanding rejections, the independent claims are not patentably distinct (as electrospun collagen is a known material), although they vary in scope, and the independent claims in copending Application No. 10/447,670 also do not recite a fiber diameter or the inclusion of engineered tissue.

In view of the foregoing, the rejection of record is maintained.

The obviousness-type double patenting rejections over claims 9-17 and 25-46 of copending Application No. 09/991,373; claims 1-2 of copending Application No. 10/409,682; and claims 1-4 of copending Application No. 10/630,624 have been withdrawn, as these three applications are now abandoned.

As noted previously, this is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1653

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

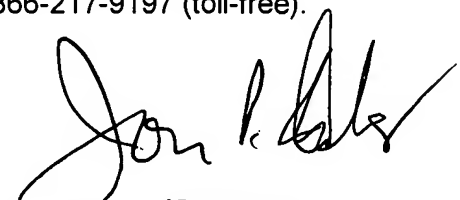
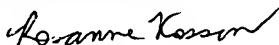
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-06-28



JON WEBER
SUPERVISORY PATENT EXAMINER